REMARKS

Applicants respectfully request reconsideration of the present application in view of the following commentary.

I. Status of the Claims

Claims 1-26, 51-53 and 107-109 were cancelled previously. Claim 27 has been amended with exemplary support in the specification, e.g., at page 5, line 15. Claim 27 also has been amended to delete the recitation of "anti-inflammatory agents," "antibiotics," and the negative proviso.

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 27-50 and 87-106 are under examination, with claims 54-86 and 110-111 withdrawn from consideration.

II. Rejection of Claims under 35 U.S.C. §112, first paragraph

Claims 27-50 and 87-106 are rejected under 35 U.S.C. §112, first paragraph, for alleged lack of written description for recitation of the negative proviso. Without acquiescing to the stated rationale of the rejection, Applicants choose to expedite the prosecution by deleting the negative limitation in question. Accordingly, withdrawal of the rejection is respectfully requested.

III. Rejection of Claims under 35 U.S.C. §102(b)

Claims 27-34, 37-47, 87-93 and 96-105 are rejected under 35 U.S.C. §102(b) for alleged anticipation by U.S. Patent No. 5,518,738 to Eickhoff et al. ("Eickhoff"). Applicants respectfully traverse the rejection.

The claimed invention is directed to an oral solid dose formulation, which comprises a nanoparticulate active agent having at least one surface stabilizer adsorbed on the surface thereof,

and surrounded by a solid dose matrix comprising at least one excipient. Eickhoff describes "a composition comprising a crystalline NSAID having polyvinylpyrrolidone adsorbed on the surface thereof, hygroscopic sugar and sodium lauryl sulfate (SLS).

The claimed invention is distinguishable from Eickhoff in the aspects: (1) that Eickhoff does not teach ***a solid dose matrix surrounding*** the nanoparticulate active agent and at least one surface stabilizer ***disintegrates or dissolves*** upon contact with saliva in less than about 3 minutes; and (2) that Eickhoff fails to disclose the active agents of the claimed invention, which are presented by a Markush group with close-ended transitional phrase "consisting of."

Because the cited art fails to teach each and every aspect to anticipate the invention, Applicants respectfully request withdrawal of the rejection.

IV. Rejection of Claims under 35 U.S.C. § 103(a)

Claims 27-50 and 87-106 are rejected under 35 U.S.C. § 103(a) for allegedly being obvious (1) over Eickhoff in view of Applicants' allegedly admitted prior art of record or U.S. Patent No. 6,177,104 to Allen et al. ("Allen"), or (2) over Eickhoff in view of Applicnants' allegedly admitted prior art of record or Allen, and further in view of PCT Publication No. WO 01/45674 by Kerkhof et al. ("Kerkhof"). Applicants respectfully traverse each ground of the rejection.

The Examiner cites the background discussion in the specification and the disclosure of Allen for the alleged teaching that it is "the routine knowledge in preparing micro- or nano-particulate compositions in a rapidly disintegrating or dissolving solid oral dose or matrix form" (Office Action, page 7, last 3 lines). However, the specification explicitly states that "[n]one of the described prior art teaches a rapidly disintegrating or dissolving, or "fast melt," dosage form in which a poorly soluble active ingredient is ***in a nanoparticulate form***" (page 4, lines 23-25; emphasis added).

Moreover, Eickhoff is targeted at reducing gastric irritation and/or achieving a more rapid onset of action by combining the NSAID with some specific ingredients, such as PVP, hygroscopic sugar and sodium lauryl sulfate, in defined ratios. *See* column 2, lines 41-47; and column 5, lines 53-57. Eickhoff further teaches that "the use of hygroscopic sugar and sodium lauryl sulfate as a combination of redispersants for the NSAID nanoparticles act synergistically in that addition of hygroscopic sugar or sodium lauryl sulfacte alone is not sufficient to redisperse the solid nanonaproxen in gastric fluid to a great extent" (column 6, lines 43-48).

Accordingly, contrary to the Examiner's suggestion of reducing particle size as taught by the secondary references (Allan and Kekhof), Eickhoff achieves the goal by a unique combination of the specific ingredients. Therefore, one skilled in the art would not have any reason to combine the references in the absence of any teaching that the ingredients of Eickhoff's composition are substitutable.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection.

V. Double Patenting Rejection

A. U.S. Patent No. 6,316,029

Claims 27-50 and 87-106 are rejected for alleged double patenting over claims 1-24 and 51-70 of U.S. Patent No. 6,316,029. Applicants choose to defer any action until the Examiner indicates that the pending claims are allowable otherwise.

B. U.S. Patent No. 6,165,506

Claims 27-50 and 87-106 are rejected for alleged double patenting over claims 1-16 and 21 of U.S. Patent No. 6,165,506, further in view of Applicants' allegedly admitted prior art. Applicants respectfully traverse the rejection.

The '506 patent describes promoting dissolution of a solid dose nanoparticulate naproxen formulation by including an alkali compound in the composition. In contrast, the claimed invention is not directed to an NSAID or a naproxen formulation. The claimed invention is further distinguishable from the '506 patent in that the claimed composition does not require an alkali compound. Therefore, Applicants respectfully request withdrawal of the double patenting rejection over U.S. Patent No. 6,165,506.

C. **U.S. Patent No. 7,276,249**

Claims 27-50 and 87-106 are rejected for alleged double patenting over claims 1-177 of U.S. Patent No. 7,276,249 and in view of Applicants' allegedly admitted prior art or Kerkhof. Applicants respectfully traverse the rejection.

The '249 patent is distinguishable from the claimed invention because it fails to disclose ***a solid dose matrix surrounding*** the nanoparticulate active agent and at least one surface stabilizer disintegrates or dissolves upon contact with saliva in less than about 3 minutes. The cited secondary reference fails to remedy the deficiencies. Therefore, the double patenting rejection over U.S. Patent No. 7,276,249 should be withdrawn.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or

incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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